UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

SHIRLEY DIANE TATOR,

Plaintiff,

v.

DAVOL, INC. and C. R. BARD, INC.,

Defendants.

Court File No.

COMPLAINT
and DEMAND FOR JURY TRIAL

Shirley Diane Tator (hereinafter "Plaintiff"), by Plaintiff's undersigned counsel, complains against Defendants Davol, Inc. and C. R. Bard, Inc. (hereafter "Davol," "Bard," or "Defendants") based upon Plaintiff's personal knowledge as to Plaintiff's own acts, and upon information and belief, as well as upon Plaintiff's attorneys' investigative efforts, as to Defendants' actions and misconduct, alleges as follows:

INTRODUCTION

Plaintiff brings this action to recover damages and/or for equitable relief, against Defendants, and each of them, who designed, manufactured, tested, marketed, distributed, promoted, and sold a product known as the Bard Composix Kugel Hernia Patch (hereinafter occasionally referred to as "the Patch" or "Bard Composix Kugel Mesh Patch"). When referring to "Defendants" in the plural from herein, Plaintiff intends by that term to mean both Defendants together and each Defendant independently in the singular.

PARTIES

1. Plaintiff, an individual resident of Montrose, Pennsylvania, sustained injury and damages associated with Plaintiff's use of Defendants' defective product, the Bard Composix Kugel Hernia Patch and due to Defendants', and each of their, negligent and otherwise wrongful conduct.

2. Defendant Davol, Inc. ("Davol") is a corporation organized and existing under the laws of Rhode Island, with its principal place of business at 100 Sockanossett Crossroad, Cranston, R.I. 02920, is a subsidiary of C. R. Bard, Inc., and together with C. R. Bard, Inc., designed, manufactured, tested, marketed, distributed, promoted, and sold the Bard Composix Kugel Hernia Patch.

3. Defendant C. R. Bard, Inc. ("Bard") is a corporation organized and existing under the laws of New Jersey, with its principal place of business at 730 Central Avenue, Murray Hill, New Jersey, 07974, is the parent company of Davol, Inc., and together with Davol, Inc., designed, manufactured, tested, marketed, distributed, promoted, and sold the Bard Composix Kugel Hernia Patch.

JURISDICTION AND VENUE

4. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because Plaintiff alleges that the amount in controversy exceeds seventy-five thousand dollars ($75,000), exclusive of interest and costs, and there is complete diversity of citizenship.

5. Venue in this Court is proper in that Davol, Inc. and C.R. Bard, Inc. conducted business in the State of Minnesota through medical device representatives in the State of Minnesota. Further, Davol, Inc. and C.R. Bard, Inc. were engaged in testing, developing, manufacturing, labeling, marketing, distributing, promoting, and/or selling, either directly or

indirectly, through third parties or related entities, the Bard Composix Kugel Hernia Patch in the State of Minnesota. Thus, a sufficient nexus exists between Defendants' forum contacts and Plaintiff's claims to justify this venue and the assertion of jurisdiction in Minnesota.

FACTUAL ALLEGATIONS

6. Plaintiff brings this action to recover damages and/or for equitable relief, against Defendants, and each of them, who designed, manufactured, tested, marketed, distributed, promoted, and sold a product known as the Bard Composix Kugel Hernia Patch.

7. A hernia is an abnormal opening or a tear in tissue that lets other organs, such as the intestine, slip through where they should not. Hernias usually appear in the groin or the abdominal wall. While some hernias can go undetected, most require surgery. As a result, some one million hernia operations take place every year in the United States.

8. The Bard Composix mesh for hernia repair was introduced in 1997. It was the first ventral, i.e., abdominal, hernia repair prosthesis that combined two biomaterials, Bard polypropylene mesh (hereinafter, PPM) and expanded polytetrafluoroethylene (hereinafter, ePTFE), in one product. The peripheral edge of the PPM is heat sealed to the ePTFE layer, resulting in two different sides to the patch. Defendants use the Composix bi-layer mesh in several of its hernia repair patches, including, but not limited to the Bard Composix E/X Mesh Patch, the Bard Composix Kugel Mesh Patch, and the Bard Composix L/P Mesh Patch. The Bard Composix Kugel Mesh Patch, Bard Composix E/X Mesh Patch, and the Bard Composix L/P Mesh Patch are almost exclusively used to repair ventral, specifically incisional hernias – hernias caused by the failure of the integrity of a prior surgical incision.

9. PPM is a heavy weight mesh that translated into a greater foreign body reaction, increasing side effects. It incites an intense inflammatory response leading to its penetration into

host tissue; the inflammatory response also creates heavy scar formation leading to decreased compliance of host tissue as well as shrinkage and contraction of the mesh. This reduces compliancy and leads to hernia recurrence as the mesh shrinks. A direct correlation between the amount of PPM and stiffness of the abdominal wall, decreased mobility, and chronic pain has been reported. Alternatively, failure of the PPM to adhere can result in separation and migration of the patch. Adhesion failures have resulted from surgeons who were improperly instructed regarding the number of sutures required to secure the patch.

10. Unlike PPM, ePFTE creates a barrier against the bowels. Barrier failures may result in bowel obstruction, adhesions, and the formation of fistulae.

11. Information gathered from the FDA's Manufacturer and User Facility Device Experience Database (hereinafter, "MAUDE"), showed that at least as early as June 2000, Defendants received reports of problems and defects in their Bard Composix Mesh patches. These reports advised of bowel adhesions and obstructions and relay surgeons' findings of the patches being "crumbled" and "delaminated".

12. The Bard Composix Kugel Mesh Patch is made of bilayered material identical to the Bard Composix E/X and Bard Composix L/P patches, but also contains a "memory recoil ring" that allows the patch to spring into place and lie flat. The Bard Composix E/X Mesh Patch and the Bard Composix L/P Mesh Patch do not contain this "memory recoil ring". The Bard Composix Kugel Mesh Patch was approved by the FDA in November of 1996, after which Defendants began marketing it and selling it. In 2002, Defendants introduced a new, larger, Bard Composix Kugel Mesh Patch.

13. Soon after the 2002 release, Defendants, despite beginning to receive a high number of reports of broken patches from doctors, continued selling the Bard Composix Kugel

Mesh Patch without informing the FDA of the increase in complaints or misinforming the FDA about complaints that were reported.

14. These reports indicated that the plastic "memory-recoil ring" tended to break (which Defendants' own studies revealed), resulting in injury to internal organs and tissue, leading to side effects including chronic intestinal fistulas (abnormal connections that form between two parts of the intestine resulting in an accumulation of bowel contents in the cavity potentially causing abscesses or infection which, in turn, can spread to the bloodstream, causing septic shock and even death), bowel obstruction (a partial or complete blockage in the intestines that can lead to infection, gangrene, or bowel perforation), and bowel perforations (caused by breakage of the memory-recoil ring, which then migrated through the abdominal wall).

15. In mid-2005, 10 complaints about ring breaks were made to Defendants over a three-month period.

16. In August 2005, Defendants stopped making the Bard Composix Kugel Mesh Extra-Large Patches, admitting that the "memory recoil ring" did not adequately withstand the stress of surgical placement.

17. On December 22, 2005, Defendants issued a Class I recall notice for several lots of the Extra-Large Bard Composix Kugel Mesh Patch. An FDA Class I recall is issued for problems related to medical devices that are potentially life-threatening or could cause a serious risk to the health of the patients implanted with the devices.

18. It was only after this recall in December 2005 that the design and manufacturing problems associated with the Bard Composix Kugel Mesh Patch became widely known.

19. On March 24, 2006, surgeons and hospital administrators learned that the recall had been expanded by Defendants to include the large oval and large circle versions of the Bard Composix Kugel Mesh Patch.

20. On December 18, 2006, the first Bard Composix Kugel Mesh Patch lawsuit was filed against Defendants in Rhode Island, alleging that the plaintiff suffered severe pain and had to undergo bowel dissection surgery, resulting in chronically inflamed bowels due to failure of the Bard Composix Kugel Mesh Patch.

21. On January 10, 2007, Defendants, having received more reports of broken memory-recoil rings, expanded the Bard Composix Kugel Mesh Patch recall.

22. On March 16, 2007, the New York Times disclosed that an FDA report secured under the Freedom of Information Act indicated that the number and severity of complaints about the Bard Composix Kugel Mesh Patch had been understated and Defendant had failed to accurately report a number of complaints it received about injuries or death related to the Bard Composix Kugel Mesh Patch.

23. All told, there have been three ever widening Bard Composix Kugel Mesh Patch recalls issued, including in December 2005, March 2006, and January 2007, encompassing six different sizes of the Bard Composix Kugel Patch: extra-large oval (7.7" x 9.7"), extra-large oval (8.7" x 10.7"), extra-large oval (10.8" x 13.7"), large oval (5.4" x 7"), oval (6.3" x 12.3") and large circle (4.5").

24. These recalls were prompted by reports of at least eighty injuries (and several deaths) associated with use of the Bard Composix Kugel Mesh Patch.

25. By the time of Defendants' first Bard Composix Kugel Mesh Patch recall, 32,000 had been sold and surgically implanted in patients.

26. Since the 10 complaints about ring breaks were made to Defendants over a three-month period in mid-2005, sales of the Bard Composix Kugel Mesh Patch had generated some $11 million in revenue for Defendants.

27. Despite the fact that Defendants were aware of manufacturing and design problems that existed in the Bard Composix Kugel Mesh Patch commencing shortly after the 2002 release of the product, they did not inform patients, doctors, or health officials of this danger.

28. Had Defendants so informed patients, doctors, and health officials, patients, whose hernia patch implants failed, could have avoided injury and even death. Instead, Defendants chose profits over patients' health, income over injury prevention, and dollars over death prevention.

29. The stated reason for the recall of the Composix Kugel Mesh Patch was a failure of the "memory recoil ring" contained in the Bard Composix Kugel patches. The following patches also contain this "memory recoil ring": Bard Ventralex Hernia Patch, Bard Kugel Hernia Patch, Bard Modified Kugel Patch, Bard CK Parastomal Patch and the Bard Polysoft Patch.

30. However, information gathered from MAUDE demonstrates that as early as August 2001, Defendants had received reports of defects and problems with the Bard Composix Kugel Mesh Patches that not only did not mention breakage or disruption of the "memory recoil ring", but did not mention the "memory recoil ring" at all. These reports advise of bowel obstructions, adhesions, constipation, and fistula resulting from the implantation of the Bard Composix Kugel Mesh Patch. These reports contain surgeons' finding of "buckled mesh",

"patch shriveling" and "edges curled up" as well as descriptions of the mesh being "crumpled", "wrinkled", "rolled up", "delaminated", and "folded".

31. At least as early as June 2000, Defendants received reports of problems and defects in the Bard Composix E/X Mesh Patch. As with the other reports, these reports advise of bowel adhesions and obstructions, intestinal fistulae, chronic abdominal pain, and separation of the layers of the patch. Both Defendants have received reports of failures in the Bard Composix Mesh Patch, the Bard Composix E/X Mesh Patch, and the Bard Composix Kugel Mesh Patch all detailing similar problems of bowel adhesions and obstructions and intestinal fistulae and describing patches as separated, delaminated, balled up, shriveled and crumpled.

COUNT I
(Strict liability – failure to warn)

32. Plaintiff hereby realleges each and every allegation set forth above, with the same force and effect as if herein repeated and set forth at length.

33. Defendants developed, manufactured, marketed, and distributed the Bard Composix Kugel Hernia Patch for sale and sold it in the course of their business and continued to do so even after acquiring knowledge that the defective devices were prone to causing injury, including potential death of the patient recipient.

34. The Patch manufactured by Defendants and implanted in Plaintiff was unreasonably dangerous when implanted due to the possibility of a malfunction resulting in serious injury or death.

35. Defendant did not give an adequate, meaningful warning regarding the significant risk of serious injury or death from its Patch.

36. As a direct and proximate result of Defendants' failure to warn of this serious risk, Plaintiff suffered damages. Specifically, as a result of having the Patch implanted in Plaintiff, Plaintiff suffered disabling pain and required surgical intervention.

37. Even after Defendants themselves discovered that the Patch was defective and dangerous, they continued long after that discovery to market and sell the Patch and thereby showed complete indifference to or conscious disregard for the safety of Plaintiff in particular and the public in general.

COUNT II
(Negligence)

38. Plaintiff hereby realleges each and every allegation set forth above with the same force and effect as if herein repeated and set forth at length.

39. Defendants designed, manufactured, tested, marketed, distributed, promoted, and sold the Bard Composix Kugel Hernia Patch.

40. When placed in the stream of commerce, its Patch was not accompanied by any meaningful warnings regarding the risk of serious injury or death associated with the Patch. The warnings given by the Defendants were silent and continued to be silent as to the defect and risk of breakage and migration even after it became known to Defendants, and as to the potential for serious injury or death.

41. Defendants had a duty to exercise reasonable care in the design, manufacture, sale, and/or distribution of its Patch, including a duty to assure that the Patch did not cause recipients to suffer serious injury or death due to the concealed breakage and migration risk posed by the device despite being used as instructed by the Defendant.

42. Defendants were negligent in the design, manufacture, testing, advertising, marketing, promotion, labeling, failure to warn, and sale of the Patch.

43. Defendants knew or should have known that recipients of the Patch, such as Plaintiff, would foreseeably suffer serious injury or death as a result of the Defendants' failure to exercise ordinary care as described above.

44. Defendants' actions as described herein constitute knowing omissions, suppression, or concealment of material facts, made with the intent that others would rely upon such concealment, suppression, or omissions in connection with the marketing of the Patch.

45. The behavior of the Defendants demonstrates that Defendants acted unlawfully and negligently, used or employed unconscionable commercial and business practices, engaged in deception, fraud, false pretenses, false promises, or misrepresentations, and/or perpetrated the knowing concealment, suppression or omission of material facts with the intent that consumers, including Plaintiff, would rely upon such concealment, suppression, or omission, in connection with the sale or advertisement of its Patch.

46. Defendants' negligence was a proximate cause of the harm suffered by Plaintiff as previously set forth herein.

COUNT III
(Fraud and misrepresentation)

47. Plaintiff hereby realleges each and every allegation set forth above with the same force and effect as if herein repeated and set forth at length.

48. Defendants made misrepresentations and omissions of material facts, including, but not limited to:

a) Representing that the Patch was fit for its intended use, when in fact, it was not and Defendants knew it was not;

b) Representing that the Patch was of merchantable quality, when in fact it was not and Defendants knew it was not;

c) Representing that the Patch was safe and efficacious in the treatment of the medical condition for which Plaintiff used the Patch, when in fact it was not and Defendants knew it was not;

d) Representing that the Patch would function as intended when necessary, when in fact it would not and Defendants knew it would not;

e) Omitting to disclose that the Patch was defective, at risk of breakage and migration, might fail to function as intended, and was thus prone to cause serious injury or death, when in fact Defendants knew of the risks; and

f) Omitting to disclose that the Patch was inherently dangerous, when Defendants knew, in fact, that it was.

49. These misrepresentations and/or omissions were false and misleading at the time they were made and were made with the intent that Plaintiff and Plaintiff's physician would rely on them and with the intent to defraud Plaintiff and Plaintiff's physician.

50. Defendants negligently and/or intentionally made the foregoing misrepresentations knowing both that they did not possess sufficient information to make the representations as truth and omitting the harmful information they did possess so as to deceive Plaintiff into believing the opposite of the truth.

51. When Defendants made the foregoing representations and omissions, they knew or should have known the representations to be false and the omissions to be material to Plaintiff's decision to use or not use the Patch.

52. In reliance upon the foregoing misrepresentations and omissions of Defendants, Plaintiff and Plaintiff's physician were induced to and did use the Patch. If Plaintiff had known of the true facts, Plaintiff would not have taken such action and risk. The reliance of Plaintiff

and Plaintiff's physician on Defendants' misrepresentations and omissions was reasonable because said representations and omissions were made by individuals and entities that were in a position to, and in fact did, know the true facts.

53. As a direct and proximate result of the foregoing misrepresentations and omissions by Defendants, Plaintiff suffered and will continue to suffer injury, disability, expense, and economic loss, for which damages Defendants are liable to Plaintiff.

COUNT IV
(Violation of the False Advertising Act, the Consumer Fraud Act, the Unlawful Trade Practices Act, and the Uniform Deceptive Trade Practices Act)

54. Plaintiff hereby realleges each and every allegation set forth above with the same force and effect as if herein repeated and set forth at length.

55. By reason of the conduct as alleged herein, and by inducing Plaintiff and Plaintiff's physician to use Defendants' product through the use of false and misleading advertising, representations, and statements, Defendants violated the provisions of Minn. Stat. §§ 325F.67, 325F.69, 325D.13, and 325D.44.

56. As a direct and proximate result of Defendant's statutory violations, Plaintiff was implanted with Defendants' Patch, which would not have occurred had Defendant not issued false or misleading advertising, representations, and statements to induce Plaintiff and Plaintiff's physicians to use the product.

57. By reason of such violations and pursuant to Minn. Stat. § 8.31, subd. 3a, § 325D.44, § 325F.67, and §§ 325F.68-70, Plaintiff is entitled to recover all of the monies paid for the product; to be compensated for the cost of the medical care arising out of the use of the product; and all consequential damages recoverable under the law including, without restriction,

both past and future medical expenses, past wage loss, loss of future earning capacity, past and future pain, suffering, disability, and emotional distress.

58. Additionally, pursuant to Minn. Stat. § 8.31, because Defendants' wrongful acts were directed not just at Plaintiff, but at the public in general, and represented conduct against which the public in general has a direct interest in protecting, Plaintiff is entitled to recover costs and disbursements, including costs of investigation and reasonable attorney's fees, and any other equitable relief as deemed appropriate by this Court.

COUNT V
(Breach of express and implied warranties)

59. Plaintiff hereby realleges each and every allegation set forth above with the same force and effect as if herein repeated and set forth at length.

60. Defendants expressly and impliedly warranted to Plaintiff that the Patch used by Plaintiff, which they designed, manufactured, and/or supplied, and/or placed in to the system of commerce for Plaintiff was of merchantable quality, fit, and safe and would not likely injure or kill Plaintiff.

61. Defendants' Patch that was implanted in Plaintiff was in fact unsafe, unmerchantable, unfit for use in the body, and otherwise injurious to Plaintiff.

62. Through their sale of the Patch, Defendants were merchants pursuant to Section 2-314 of the Uniform Commercial Code.

63. Defendants breached express and implied warranties of merchantability in the sale of Defendants' defective Patch to Plaintiff in that the Patch was not fit for the ordinary purposes intended by Defendants and described above.

64. As a direct and proximate result of Defendants' breach of their express and implied warranties as described herein, Plaintiff suffered and will continue to suffer injury,

disability, expense, and economic loss as previously described, rendering Defendants liable for said damages.

COUNT VI
(Strict liability – defective design)

65. Plaintiff hereby realleges each and every allegation set forth above with the same force and effect as if herein repeated and set forth at length.

66. At all times relevant to this Complaint, Defendants were engaged in the design, manufacture, and sale of the Patch.

67. The Patch as designed by Defendants was defective.

68. As a result of Defendants' defective design, the Defendants' Patch was unreasonably dangerous to the Plaintiff at the time Defendants sold it, and at the time it was implanted in Plaintiff and used for its intended purpose.

69. When they manufactured and at the time they sold the Patch to Plaintiff, Defendants were aware of the purpose and the manner of Patch's use. Defendants knew that the Patch would reach Plaintiff without substantial and/or significant change in the condition in which Defendants sold it, and the Patch in fact did reach Plaintiff without substantial and/or significant change in condition.

70. Failure of the Patch leads to, among other serious injuries, death.

71. As a result of Defendants' defective design of the Patch, Plaintiff has been and is continuing to be damaged as more fully set forth above.

72. Defendant is thereby liable to Plaintiff for Plaintiff's damages sustained as a direct and proximate result of Plaintiff's use of the Patch.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a jury trial as to all claims so triable in this action.

RELIEF SOUGHT

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, for damages, as well as all costs of this action, to the fullest extent of the law including:

A. Damages to compensate Plaintiff for injuries sustained as a result of use of Defendants' Patch, past and future lost income, past and future medical expenses as proven at trial;

B. Physical pain and suffering of Plaintiff;

C. Pre- and post-judgment interest at the lawful rate;

D. Reasonable attorneys fees and costs; and

E. Such other applicable damages as the Court deems appropriate.

Dated: March 3, 2010

LAW OFFICES OF CHARLES H. JOHNSON, PA

/s/ Charles H. Johnson (#50696)

Charles H. Johnson, Esq.
bdehkes@charleshjohnsonlaw.com
Anna M. Yakle, Esq. (#389158)
ayakle@charleshjohnsonlaw.com
Attorneys for Plaintiff
2599 Mississippi Street
New Brighton, MN 55112-5060
Telephone: (651) 633-5685
Fax Phone: (651) 633-4442